Complaint 1089/2012/BEH to the Ombudsman about the European Food Safety Authority (EFSA)
With particular reference to neonicotinoids, risk assessment of honey bees, glyphosate, GMOs and raising the Maximum Residue Limits (MRLs) for crops at the request of industry

With regard to honeybees and neonicotinoids, the Austrian Ombudsman has complained that the European Commission (EC) has not taken into account the new research on bees. The EC has to reply by 30th June 2012. The EFSA Report on Risk Assessment was published in April 2012, and was followed by an annexe about the new research, published 1st June 2012.

The neonicotinoids were registered illegally according to the Directive on Plant Protection Products (EC) 1107/2009. In Annex II, page 43, persistence in the soil, approval should not be given if the half-life in soil is greater than 120 days (*'based on half-life data collected under appropriate conditions, which shall be described by the applicant'*). http://www.epa.gov/opprd001/factsheets/clothianidin.pdf is the conditional registration document for clothianidin issued to the applicant in 2003. The aerobic soil metabolism half-life under a variety of soil conditions was 148-1,155 days and the terrestrial field dissipation was 277-1,386 days. The US EPA excluded a figure at the top end, the extrapolated half-life of which was 6,931 days (2005). However, other EPAs have recorded soils in which there was no dissipation of clothianidin. Persistence in the environment is a characteristic of all the chloronicotinyl family of pesticides, since chlorine does not occur in nature. Imidacloprid should not have been registered either (New York State quoted the half-life of imidacloprid in soil as "*ranging from 120-365 days*"). In addition, clothianidin is a metabolite of thiamethoxam *('in calculating Maximum Residue Limits (MRLs) the sum of thiamethoxam is expressed as thiamethoxam'*).

In January 2011, Bayer, Syngenta, Dow, DuPont, BASF, Monsanto, SETAC and the US EPA admitted that there were no risk assessments suitable for systemic pesticides
The Summary Report of the SETAC Workshop on Pesticide Risk Assessment for Pollinators in Florida, January 2011 was written by Dr David Fischer of Bayer CropScience and Thomas Moriarty US EPA Office of Pesticide Programs. On page 12, the authors said: *"Many who are familiar with pesticide risk assessment recognize that the methodology and testing scheme for foliar application products (where exposure may be primarily through surface contact) is not adapted to assess potential hazard and risk from systemic pesticides".*
So, for many years, the systemic pesticide risk assessments have been totally inadequate.
http://www.setac.org/sites/default/files/executivesummarypollinators_20sep2011.pdf
The workshop was by invitation only. Four of the experts advising the EFSA were delegates. They would have known that the risk assessment process for the neonicotinoids insecticides was grossly flawed. A fifth, Dr Jochen Pflugfelder of the Swiss Bee Research Center, in an interview on May 23rd 2012, when asked about the 50% overwintering losses of Swiss bee colonies, placed the blame entirely on the *Varroa* mite.

The EC does not require Member States to measure levels of neonicotinoids (or glyphosate) in surface-water or groundwater or soil (in spite of years of increasing use). Thus, the EFSA assessments have failed to take into account existing residues in soil and water, or evidence of their uptake in wild plants. As early as 1996, The New York State Environment Protection Agency was concerned about accumulating levels of imidacloprid. By 2003/2004, high levels were found in private wells, golf courses and areas of tree injection. For the safety of their residents, the Health Board decided to limit the registration of imidacloprid. As far as we know, clothianidin was never registered because of its

persistence. In 2008, California's Department of Pesticide Regulation demanded re-evaluation of imidacloprid, because their own residue evaluation studies showed a) high levels of imidacloprid in leaves and blossoms of treated plants and b) increases in residue levels over time. Residues in some plants measured higher than 4 ppm. When using soil application, imidacloprid levels remained relatively low for the first six months after application, followed by a dramatic increase that remained stable in some cases for more than 500 days after treatment. They found the use of *imidacloprid* on an annual basis was additive; significant residues from the previous season appear to be available to the treated plant. Preliminary results from studies of *imidacloprid* residues in eucalyptus nectar and pollen indicate residues in nectar at levels of up to 550 ppb. They found in some plants the levels were found to be more than 20 times the estimated LC50 of 185 ppb on bees. Since the neonicotinoids share many of the same characteristics as imidacloprid, California DPR said that clothianidin, dinotefuran and thiamethoxam should be included in this re-evaluation process. The US EPA has succeeded in delaying the start of this re-evaluation until 2012.

Field Study measuring clothianidin and thiamethoxam in maize fields
Krupke *et al* in 2012 (for references see Evidence Doc) study of clothianidin and thiamethoxam levels in bees in maize fields in Indiana, found neonicotinoids in the soil of each field they sampled, including unplanted fields. Plants visited by foraging bees (dandelions) growing near these fields were found to contain neonicotinoids as well. This indicates deposition of neonicotinoids on the flowers, uptake by the root system, or both. Dead bees collected near hive entrances during the spring sampling period were found to contain clothianidin as well, although whether exposure was oral (consuming pollen) or by contact (soil/planter dust) is unclear. They also detected the insecticide clothianidin in pollen collected by bees and stored in the hive. When maize plants in the field reached anthesis, maize pollen from treated seed was found to contain clothianidin and other pesticides; and honey bees in their study readily collected maize pollen. *"We know that these insecticides are highly toxic to bees; we found them in each sample of dead and dying bees,"* said Christian Krupke, Associate Professor of Entomology at Purdue and a co-author of the study. Bees also suffered from tremors, uncoordinated movement and convulsions, which are all signs of insecticide poisoning. *"This material is so concentrated that even small amounts landing on flowering plants around a field can kill foragers or be transported to the hive in contaminated pollen,"* Krupke said. *"It stands out as being an enormous source of potential environmental contamination, not just for honeybees, but for any insects living in or near these fields. The fact that these compounds can persist for months or years means that plants growing in these soils can take up these compounds in leaf tissue or pollen."*

18 April 2012 the EFSA published a Report: Scientific Opinion on the science behind the development of a risk assessment of Plant Protection Products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees) EFSA Panel on Plant Protection Products and their Residues (PPR) European Food Safety Authority (EFSA), Parma, Italy, 275 pages.

This document is not science, but a cynical parody of it. The EFSA cannot be taken seriously as a scientific organisation when it has no knowledge of the baseline levels in soil, surface and ground-water. These are merely delaying tactics to keep the neonicotinoids on the market, just as the SETAC Workshop was in January 2011. In fact, the recommendations for further research are very similar to those of the SETAC Summary Report. If actually followed up and developed, most of them would take the industry and protection agencies many years to achieve. Many are very basic to safety, such as chronic toxicity studies on honey bees and larvae. In the case of most of the items for future research, the studies have

already been done by independent scientists and have been published in peer-reviewed journals. Many scientific studies from around the world now confirm the acute and chronic toxic effects of systemic neonicotinoid pesticides on bees. The following are just a small sample from literature; sub-lethal exposure makes bees susceptible to infections and increases mortality; sub-lethal exposure causes abnormal foraging behaviour; ingestion of dust from maize coated seeds during sowing kills bees; consumption of guttation drops in seedlings cause death and independent laboratory tests show that neonicotinoids are toxic to bees.

The SETAC workshop had been announced with a fanfare on 26/03/2010, more than 2 years ago. *"(It is) intended to bring together the best available science regarding exposure and effects assessment… The development of a risk assessment process for pollinators and identification of the data needed to inform that process relies on a clear articulation of the risk management goals. To that end, reasonable and concise problem formulations are a critical first but iterative stage where stakeholders can play a pivotal role."*

The Reasoned Opinion group of the EFSA has readily granted 'modification' (i.e. increases) of maximum residue limits (MRLs) at the request of the pesticides industry
In a period of 4 months (from February 2012), the EFSA has approved 22 proposals by the Pesticides Industry to increase MRLs for pesticides in crops: *"in order to accommodate intended uses*". Sometimes the reason is: *"to accommodate for the international trade"*
In the case of fluopicolide '*for radishes, onions, kale and potatoe*s' in various countries Bayer CropScience was granted approval "*to raise the existing MRLs*" without even specifying the levels. Bayer had "carte blanche" approval.

Examples relevant to this complaint
Monsanto Europe asked the EFSA to set the import tolerance for glyphosate in lentils "*in order to accommodate the authorised desiccation use of glyphosate in lentils in the US and Canada*" from 0.1 mg/kg to 10 mg/kg (i.e. 100 times). (January 2012) The EFSA had granted similarly elevated MRLs for glyphosate on wheat and GM soya. Presumably it is in anticipation of Roundup® Ready GM Crops, when increased spraying has to cope with the herbicide resistant weeds.
Syngenta Crop Protection BV for thiamethoxam (clothianidin) asked the EFSA to grant an increase of MRL on carrots (Approved February 2010)
Syngenta Agro SA asked for an increase in MRL of thiamethoxam (clothianidin) in strawberries and beans with pods from 0.05 mg/kg to 0.3 mg/kg (i.e. six times). (Approved June 2010).

EFSA have recently approved old herbicides at the request of industry
This is in anticipation of GM technology coming to Europe, in order to increase the strategies for the inevitable development of herbicide (glyphosate) resistance in plants. (Pests can also develop resistance to insecticides too). The introduction of GMO herbicide-tolerant crops in the US in 1996 resulted in an increase of 383 million pounds of herbicide use in the first 13 years. This is as a result of the emergence of glyphosate-resistant (GR) weeds. The first GR weed population confirmed in the U.S. in 1998 was rigid ryegrass, (within 2 years) infesting several thousand acres in California almond orchards. Less than a decade later, GR biotypes of nine species are now found in the U.S. and infest millions of acres of cropland in at least 22 States. Particularly troublesome are Pigweed, Horseweed and Giant Ragweed whose infestations can sometimes cause cropland to be abandoned. Each year more pesticides, or different or older ones, including paraquat, have to be applied. In 2005, the US EPA evaluated for re-registration 2,4-D, an old herbicide and a component of Agent Orange. The

US EPA determined that 2,4-D was eligible for re-registration but required certain changes to uses on the label to mitigate risk. Weed scientists say that US farmers are locked in a '*pesticide treadmill*.'

Economics for US farmers; written in 2009

"The economic picture dramatically darkens for farmers combating resistant weeds under average soybean yields (36 bushels) and market prices ($6.50 per bushel). Such average conditions would generate about $234 in gross income per acre. The estimated $80 increase in 2010 costs per acre of HT soybeans would then account for one-third of gross income per acre, and total cash operating costs would exceed $200 per acre, leaving just $34 to cover land, labor, management, debt, and all other fixed costs. Such a scenario leaves little or no room for profit at the farm level."

Similar figures were quoted from rural communities in Argentina. In 1996 they were spraying <2 litres/hectare of glyphosate; by 2010 glyphosate use had increased to 10 litres/hectare.

EFSA approval for new/old pesticides

2,4-D (one half of the infamous *Agent Orange*, used as a defoliant during the Vietnam War). Its effects on human health are uncertain, but veterans exposed to this chemical had increased risk of non-Hodgkin's lymphoma. The EPA has suggested it has endocrine disruption potential in mammals. In the US, Dow has applied for a GMO corn that is tolerant to 2,4-D and glyphosate. 2,4-D was re-registered in the EU in 2002 and Greece is in the process of revising the existing MRLs in crops and in meat; many have been recommended for use. Published November 2011.

Quizalofop, a new herbicide, had its MRLs increased for use on sunflowers and cotton 27/10/2011. Little is known about it.

Dicamba Syngenta Crop Protection asked for Dicamba (spray) to be approved as a herbicide on maize and pasture. Approved 17/12/10.

Glufosinate is an old herbicide which was banned in several European Countries. Independent research shows that it is teratogenic in mice and rats and affects the glutamate receptors in the brains of immature or foetal rats. It is a suspected carcinogen which doubled the incidence of birth defects in children of pest applicators. In the EU it was included in Annex 1 on 1/10/2007 and Bayer CropScience submitted an updated doc in September 2009 which was evaluated in Sweden. Despite risks to non-target arthropods and small herbivorous mammals and a high long-term risk for mammals, the EFSA approved it in March 2012.

Refusal to ban glyphosate

There is independent evidence of the harmful effects of glyphosate on humans (see evidence doc) which the EC/EFSA has ignored. Why has the EC ignored requests from independent scientists who warned about the toxic effects of Roundup® on humans, at the low levels found in the environment? Why was Dr Graciela Gomez, an Argentinian lawyer, turned away when she came to petition the EU in March 2012 about Roundup® Ready Soya which was associated with congenital birth defects, reproductive problems and cancers in the South American rural communities? She was told that glyphosate wouldn't be reassessed in the EU until 2015 (instead of 2012). Plants can develop resistance to herbicides, and pests can develop resistance to insecticides, but humans can't. Instead, with continuous chemical exposure in the environment and in foods, genetic damage can lead to teratogenesis or carcinogenesis (see human and pig congenital defects in the Evidence to EC doc.)

06/06/2012.

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